

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION**

D. BLAINE LEEDS, DDS and
SMILEDIRECTCLUB, LLC,

Plaintiffs

v.

BOARD OF DENTAL EXAMINERS OF
ALABAMA; ADOLPHUS M. JACKSON,
DMD; T. GERALD WALKER, DMD;
DOUGLAS BECKHAM, DMD; STEPHEN
R. STRICKLIN, DMD; MARK R.
MCILWAIN, DMD, MD; KEVIN M.
SIMS, DMD, MS; SHERRY S.
CAMPBELL, RDH, CDHC; individually
and in their official capacities as Members
of the Board of Dental Examiners of
Alabama,

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs Dr. D. Blaine Leeds, DDS (“Dr. Leeds”) and SmileDirectClub, LLC (“SmileDirect”) allege the following claims against Defendants, the Board of Dental Examiners of Alabama (the “Board”) and Adolphus M. Jackson, T. Gerald Walker, Douglas Beckham, Stephen R. Stricklin, Mark R. McIlwain, Kevin M. Sims, and Sherry S. Campbell, individually and in their official capacity as Members of the Board of Dental Examiners of Alabama.

INTRODUCTION

Dr. Leeds, who is an Alabama state licensed dentist, in conjunction with the non-clinical support services provided by SmileDirect, provides clear aligner therapy treatment to Alabama patients. One of the services that SmileDirect provides to Dr. Leeds is a physical location, a “SmileShop” where consumers can have photographs of their teeth and gums taken that can then

be shared with Dr. Leeds. The only services provided at the SmileShop location are the collection of photographs. The photographs are not x-rays, do not penetrate the gums, oral tissues or teeth, and do not use gamma rays. The photographs are then sent to Dr. Leeds so that he may review these photographs in addition to the other information that is supplied to him by the consumer in determining whether the consumer is a candidate for clear aligner therapy treatment. If Dr. Leeds approves the use of clear aligner therapy treatment, and the consumer elects to move forward with the treatment, Dr. Leeds writes a prescription to a lab to have the clear aligners fabricated and shipped. Dr. Leeds is solely responsible for determining, managing, and overseeing his patient's care throughout the entire time the patient is receiving clear aligner therapy treatment.

1. Dr. Leeds is an out-of-state dentist with an Alabama license who has contracted with SmileDirect to use its non-clinical dental support organization services, including SmileDirect's teledentistry platform, to provide low-cost clear aligner therapy treatment to patients in the state of Alabama.

2. Recently, the Board of Dental Examiners of Alabama (the "Board") took the position that the taking of photographic images of consumers' teeth and gums by SmileDirect's SmileShop employees constitutes the unlicensed practice of dentistry within the meaning of Alabama Code § 34-9-6(7). The Board's position also means that Dr. Leeds is not permitted to provide certain services to patients unless he is physically present in the State of Alabama. This facially discriminatory and blatantly protectionist position by the Board is inconsistent with the stated purpose and express language of the Alabama Dental Practice Act. *See* Ala. Code § 34-9-1 *et seq.*

3. The Board's position is outside the scope of its authority, unlawfully burdens and discriminates against out-of-state dentists like Dr. Leeds and out-of-state companies like

SmileDirect, restricts Alabama residents' access to affordable clear aligner therapy treatment, fails to protect the public in any manner, stifles competition, harms consumers, and makes it virtually impossible for Dr. Leeds to provide dental services to Alabama patients across state lines or for SmileDirect to lawfully conduct its interstate business as to consumers in the State of Alabama. These costly and prohibitive changes to SmileDirect's and Dr. Leeds' respective present business models serve no purpose other than protectionism. Moreover, the Board's position has no positive bearing on, or substantial relation to, the public health, safety, or morals, or the general welfare, the public convenience, or to the general prosperity. In this regard, the Board's actions violate federal antitrust statutes and constitutional guarantees, including the Commerce Clause and the Equal Protection and Due Process guarantees of the Fourteenth Amendment.

THE PARTIES

4. Plaintiff Dr. Leeds is an Alabama-licensed dentist residing in Nashville, Tennessee who contracts with SmileDirect for the use of its non-clinical support services in order to offer clear aligner therapy treatment to patients, including patients located in the state of Alabama. Dr. Leeds is a citizen of Tennessee.

5. Plaintiff SmileDirect is a corporation organized under the laws of Tennessee, with its principal place of business in Tennessee. Accordingly, SmileDirect is a citizen of Tennessee. SmileDirect provides non-clinical support services to contractually-affiliated dental practices that wish to offer doctor-directed, remote, clear aligner therapy treatment to patients with mild to moderate malocclusion (*i.e.* improper positioning of the teeth when the jaws are closed). SmileDirect is licensed to practice business in the State of Alabama. All aligners sold in Alabama are prescribed by Alabama-licensed dentists like Dr. Leeds who have engaged SmileDirect to provide these non-clinical support services.

6. SmileDirect has over 150 SmileShops across the country and recently opened its first Alabama SmileShop location at 710 Inverness Corners, Birmingham, Alabama.

7. The Board of Dental Examiners of Alabama consists of seven members, which include “six dentists” and one “dental hygienist.” Ala. Code § 34-9-40. The Board and each of its members is a citizen of Alabama. The Board’s authority is limited to regulating the practice of dentistry and dental hygiene and those who practice dentistry or dental hygiene in the State of Alabama. The Board has no authority over activities that do not constitute dentistry or dental hygiene or individuals and organizations, such as SmileDirect and its employees (referred to as SmileGuides), who provide only non-clinical support services to dental providers. These SmileShop employees simply take photographs; they are not dental assistants or dental hygienists, and in 2018, the Alabama legislature withdrew from the Board the authority to regulate expanded duty dental assistants in any event.

8. Defendant Adolphus M. Jackson is the President of the Board. Upon information and belief, Dr. Jackson practices general dentistry in Birmingham, Alabama. Dr. Jackson is a citizen of Alabama.

9. Defendant T. Gerald Walker is the Vice President of the Board. Upon information and belief, Dr. Walker is a practicing dentist in Trussville, Alabama. Dr. Walker is a citizen of Alabama.

10. Defendant Douglas Beckham is the Secretary-Treasurer of the Board. Upon information and belief, Dr. Beckman practices general dentistry in Birmingham, Alabama. Dr. Beckham is a citizen of Alabama.

11. Defendant Stephen Stricklin is a current member of the Board. Upon information and belief, Dr. Stricklin is a practicing dentist in Alabaster, Alabama. Dr. Stricklin is a citizen of Alabama.

12. Defendant Kevin M. Sims is a current member of the Board. Upon information and belief, Dr. Sims practices dentistry in Birmingham, Alabama. Dr. Jackson is a citizen of Alabama.

13. Defendant Mark R. McIlwain, is a current member of the Board. Upon information and belief, Dr. McIlwain practices dentistry in Sheffield, Alabama. Mr. McIlwain is a citizen of Alabama.

14. Defendant Sherry S. Campbell, is a current member of the Board. Upon information and belief, Ms. Campbell is a practicing dental hygienist. Ms. Campbell is a citizen of Alabama.

JURISDICTION AND VENUE

15. The Court has subject matter jurisdiction over Counts One, Two, Five through Eight, and Eleven pursuant to 28 U.S.C. §§ 1331, 1343, as Plaintiffs are asserting claims under the Constitution and the laws of the United States, including claims pursuant to 42 U.S.C. § 1983.

16. The Court has subject matter jurisdiction over Counts Three, Four, and Eleven pursuant to 28 U.S.C. §§ 1331, 1337, as Plaintiffs are asserting claims under the laws of the United States, and more particularly claims under the federal Sherman Act.

17. The Court has supplemental jurisdiction over Counts Nine and Ten pursuant to 28 U.S.C. § 1367(a).

18. This Court also has subject matter over all Counts pursuant to 28 U.S.C. § 1332, in that this is an action between citizens of different states, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

19. The Board was created by the Alabama Legislature. *See* Ala. Code §§ 34-9-40 *et seq.* The Board operates in the State of Alabama and the events giving rise to the claims asserted in this Action occurred in the State of Alabama. Defendants Jackson, Walker, Beckham, Stricklin, McIlwain, Sims, and Campbell are all citizens of the State of Alabama. Accordingly, Defendants are subject to personal jurisdiction in Alabama.

20. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 15 U.S.C. § 22 because upon information and belief Defendants Jackson, Walker, Stricklin, McIlwain, and Sims all reside in this District and the Board is deemed to reside in any judicial district in which it is subject to personal jurisdiction with respect to this Action, which includes this District. Venue is also proper in this District because a substantial part of the events or omissions giving rise to the claims asserted in this Action occurred in this District.

21. The Defendants' actions substantially and adversely affect interstate commerce in the "relevant market" as described herein. Plaintiffs and Defendants provide services in interstate commerce and certain of the Defendants perform clear aligner therapy treatment using products that are sold across state lines and from outside the State of Alabama into the State of Alabama. In addition, by restraining competition for clear aligner therapy treatment in Alabama, the flow of interstate commerce is interrupted because the aligner products offered by Plaintiffs are sent to Alabama consumers across state lines. Thus, Defendants' actions have the effect of reducing the amount of interstate commerce to the detriment of consumers.

FACTUAL BACKGROUND

SmileDirect Provides Non-Clinical Support Services to Licensed Dental Providers.

22. SmileDirect provides non-clinical support services, including a web-based teledentistry platform, that licensed dentists and orthodontists use to connect with their patients

with mild to moderate malocclusion who are seeking corrective teeth realignment through the use of clear aligner therapy treatment. In Alabama, SmileDirect provides non-clinical support services to contractually-affiliated dental practices of Alabama-licensed dental professionals who wish to use its platform and non-clinical support services to offer doctor-directed, remote, clear aligner therapy treatment. Clear Aligners are a series of custom-made removable plastic retainers that are placed on an individual's teeth and designed to move the teeth in small increments until the desired positioning is achieved. Teledentistry enables the provision of dental treatment and care via remote technology, rather than on-site personal contact with patients.

23. The Alabama legislature has determined that the practice of dentistry across state lines and the technology associated therewith are in the public interest and intended the Alabama Dental Practice Act to promote such evolution in dentistry. Ala. Code § 34-9-2.

24. Through SmileDirect's teledentistry platform, Dr. Leeds—as well as other dentists and orthodontists licensed in the State of Alabama who affiliate with SmileDirect—are able to provide remote clear aligner therapy treatment at a substantially lower price than traditional aligner therapy treatment offered in local brick and mortar dental offices, and are therefore able to treat many patients who otherwise would not be able to afford traditional orthodontics. The SmileDirect platform is built around its proprietary SmileCheck system, a web-based portal that connects patients and doctors, facilitating timely and convenient interaction.

25. Dr. Leeds' practice and other dental practices that engage SmileDirect to provide its non-clinical support services and teledentistry platform are revolutionizing orthodontic treatment by dramatically lowering the price of clear aligner therapy treatment for mild to moderate cases of malocclusion and enabling greater access to clear aligner therapy treatment for the residents of the State of Alabama.

26. SmileDirect's mission of providing affordable clear aligner therapy treatment to the underserved is important in the State of Alabama, where approximately 63% of the counties do not have a single licensed orthodontist.

27. Among the suite of non-clinical support services offered by SmileDirect is the provision of a SmileShop for SmileDirect-affiliated licensed dentists and orthodontists, including Dr. Leeds.

28. SmileShops are locations where consumers may have photographs taken of their teeth and gums through the use of an iTero (a device which stores or processes these photos digitally to create a scan), to assist their state-licensed treating dentist in his or her determination of whether such consumers are candidates for clear aligner therapy treatment. The only sense in which the imaging performed by the iTero is digital is that its photographic images are stored on digital storage media instead of film. The iTero does not utilize ionizing radiation, x-rays, gamma rays, or any similar radiation and does not penetrate the gums, oral tissues, or teeth. In fact, Defendant Walker himself states on his website in referring to a similar camera that "One of the biggest advantages" is that it "does not expose patients to radiation." Consequently, the iTero is cleared as safe and effective by the FDA. Furthermore, because it is merely taking photographic images, unlike devices that are used for medical or invasive imaging procedures, such as x-ray machines, the iTero does not need to be registered with or inspected by the State prior to use. Digital photographs such as those created by the iTero are necessary for SmileDirect's licensed dentists and orthodontists to provide clear aligner therapy treatment and thereby compete in the "relevant market" as defined below.

29. The digital photographs taken at the SmileDirect SmileShop in Alabama are performed by employees trained in using an iTero, which is essentially a wand with a camera, to

rapidly take thousands of photographs of a consumer's teeth and gums. On Defendant Walker's website, he describes a similar camera as being "the size and shape of a pen. It is covered with a disposable sheath, to ensure that no germs are transmitted from patient-to-patient." Defendant Jackson, on his website, similarly describes it as "small, about the size of the mirror we use during your regular hygiene appointment. You probably wouldn't even notice we're using it."

30. The SmileShop employees also take standard digital photographs of the consumer's teeth and gums using a regular digital camera. These photographs are also provided to Dr. Leeds, or another Alabama-licensed dentist or orthodontist, for review and evaluation to identify periodontal disease, cavities, or any other presentation that would require further clearance or prevent the consumer from being a candidate for SmileDirect clear aligner therapy treatment.

31. The iTero photographs are sent to a dental lab and from these photos they create a 3D model treatment plan which—along with the standard photographs, the consumer's health and dental histories, and other pertinent information—are reviewed and evaluated by Dr. Leeds or another Alabama-licensed dentist or orthodontist.

32. The Alabama-licensed dentist or orthodontist also determines whether any additional information, x-rays, or further photographs are required or appropriate. If so, the dentist indicates what additional information is required before a treatment decision can be made. In addition, each patient is required to affirmatively state, in writing and before commencing clear aligner therapy treatment, that they have seen their regular dentist within the six-month period prior to commencing treatment and that they will continue to see their regular dentist throughout the course of their treatment.

33. Each use of the iTero in the Alabama SmileShop is supervised by Dr. Leeds or another Alabama-licensed dentist or orthodontist by reviewing and evaluating the photographs and

the 3D model resulting therefrom and by determining whether any additional information is required or appropriate, such as additional use of the iTero.

34. Throughout the process, the Alabama-licensed dentist or orthodontist maintains sole responsibility for all clinical decisions, including evaluating, diagnosing, and, if appropriate in the licensed dentist's or orthodontist's independent professional judgment, treating the patient's condition with clear aligner therapy treatment.

35. Like Dr. Leeds, each SmileDirect-affiliated dentist or orthodontist who utilizes a SmileDirect product or service to treat an Alabama resident is licensed and qualified to practice dentistry as to patients in the State of Alabama.

36. SmileDirect's entry into the market and affiliation with dentists like Dr. Leeds who prescribe clear aligner therapy treatment for their patients has been embraced by many in the public and dental community. Through the use of SmileShops and SmileDirect's web-based teledentistry platform, SmileDirect has been able to drastically reduce the cost of expensive (and often overpriced) clear aligner therapy treatment and increase access to clear aligner therapy treatment for many otherwise unreachable segments of the population, all while ensuring that patients receive treatment from and are closely monitored by state licensed dentists and orthodontists.

37. Since SmileDirect opened its first SmileShop in Alabama approximately two months ago, SmileDirect has taken nearly six hundred digital photographic scans for consumers in Alabama without a single incident or complaint of physical injury, infection, or other adverse patient outcome associated with the taking of a digital photographic scan. In addition, SmileDirect has taken hundreds of thousands of digital photographic scans on a national basis without a single such incident or complaint.

Alabama Dental Practice Act.

38. The Alabama legislature has enacted the Alabama Dental Practice Act, one of the purposes of which is to encourage the practice of dentistry across state lines and the technology that enables it. Ala. Code § 34-9-2(b) provides:

The Legislature also finds and declares that, because of technological advances and changing practice patterns, the practice of dentistry and the practice of dental hygiene is occurring with increasing frequency across state lines and that the technological advances in the practice of dentistry and in the practice of dental hygiene are in the public interest.

39. The Alabama Dental Practice Act defines what constitutes the practice of dentistry, stating, in part:

Any person shall be deemed to be practicing dentistry who does any of the following...

...

(7) Uses a roentgen, radiograph, or digital imaging machine for the purpose of making dental roentgenograms, radiographs, or digital images, or who gives, or professes to give, interpretations or readings of dental roentgenograms, radiographs, or digital images, or radiographic or roentgen therapy.

Ala. Code § 34-9-6.

40. The Alabama Dental Practice Act goes on to exempt certain practices and operations by providing, in part:

1. Nothing in this chapter shall apply to the following practices, acts, and operations:

...

(5) The use of roentgen machines or other means for making radiographs, digital images, or similar records of dental or oral tissues under the supervision of a licensed dentist or physician;

provided, that the services shall not be advertised by any name whatever as an aid or inducement to secure dental patronage, and no person shall advertise that he or she has, leases, owns, or operates a roentgen or other machine for the purpose of making dental radiographs or images, of the human teeth or tissues or the oral cavity, or administering treatments thereto for any disease thereof.

Ala. Code § 34-9-7.

41. Accordingly, as the statutory language bears out, the practice of dentistry across state lines via technological advances has been expressly encouraged by Alabama's legislature. Likewise, the making of "digital images, or similar records of dental or oral tissues" is not considered the unlicensed practice of dentistry where the images are made "under the supervision of a licensed dentist or physician." *Id.*

42. Neither "supervision" nor "digital images" is defined in the statute or its associated regulations.

The Alabama Dental Board and Its Regulations.

43. The Alabama Dental Practice Act establishes the Board of Dental Examiners. Ala. Code § 34-9-40.

44. Pursuant to Ala. Code § 34-9-43, "The board shall exercise, subject to this chapter, the following powers and duties: . . . (2) Prescribe rules for qualification and licensing of dentists and dental hygienists."

45. The Board promulgates regulations, but is authorized to do so only to the extent specified in the Act.

46. In 2018, the Dental Practice Act was amended to discontinue the licensing and regulation of expanded duty dental assistants and to remove all references to expanded duty dental assistants.

47. Accordingly, the Dental Practice Act does not currently provide the Board with the authority to regulate expanded duty dental assistants.

48. The Board has promulgated a regulation purporting to regulate what it calls allied dental personnel, even though they are not all dentists or dental hygienists. Ala. Admin. Code r. 270-X-3-.10 states:

Allied dental personnel are dental hygienists, dental assistants and dental laboratory technicians.

Subject to the prohibition that no intra-oral procedure can be performed unless under the direct supervision of a duly licensed dentist as defined by Board rule, the following allied dental personnel may perform the following:

...

(2) Dental Assistants and Dental Hygienists:

...

(o) Make dental radiographs or digital images.

49. This regulation was issued before, and has not been revised since, the amendment of the Dental Practice Act to discontinue the Board's authority to regulate expanded duty dental assistants.

50. "Direct supervision" is further defined by the Board's regulation as "supervision by a dentist who authorizes the intraoral procedure to be performed, is physically present in the dental facility and available during performance of the procedure, examines the patient during the procedure, and takes full professional responsibility for the completed procedure." Ala. Admin. Code r. 270-X-3-.06. At least to the extent applied to photographic images taken by non-clinical staff under the supervision of out-of-state dentists who are licensed in Alabama, this regulation is

outside the authority conferred on the Board by the Dental Practice Act, and contrary to the express statutory objectives of said Act.

51. The Dental Board's expansion of the Act's requirement for "supervision" of the use of "digital imaging machines" to require in-person "direct supervision" of mere photographs stored or processed digitally is neither authorized by nor consistent with the Dental Practice Act.

The Board Interprets Unlawful Practice of Dentistry to Reach SmileDirect.

52. In or prior to September 2018, the Board met to discuss SmileDirect. The Board had received a complaint from a competing Alabama-licensed dentist about SmileDirect's operations. The Board directed its investigator to visit SmileDirect's SmileShop in Alabama and deliver a cease and desist letter unless there was an Alabama-licensed dentist on site.

53. On September 20, 2018, the Board sent SmileDirect a cease and desist letter alleging SmileDirect was engaged in the unlawful practice of dentistry. The letter does not provide SmileDirect a fair and accurate explanation of what conduct is alleged to be unlawful and why.

54. On October 3, 2018, representatives from SmileDirect met with the Board to explain both the function of the iTero—that it is a form of simple photography that has no potential for adverse events or patient harm and does not constitute a dental procedure—and the involvement of an Alabama-licensed dentist or orthodontist in the overall process.

55. On October 9, 2018, the Board emailed counsel for SmileDirect, stating "Thank you for coming by the Board office last week to discuss Smile Direct Club. I reviewed the situation with the Board last Friday in detail. I was directed to inform you that your client immediately must cease and desist performing the services that are considered the practice of dentistry (i.e. digital imaging) without a supervising dentist present." In a follow up phone call between counsel for SmileDirect and Board prosecutor Donna Dixon, Dixon said that the Board's view is that this is

clear cut and simple in that digital imaging is defined in the statute as the practice of dentistry and so requires direct dentist supervision.

56. On information and belief, the Board’s position is based on Ala. Code § 34-9-6(7) and one of its own regulations, Ala. Admin. Code r. 270-X-3-.10. Specifically, the Board considers SmileDirect’s taking of photographic images of the potential consumer’s teeth and gums under the supervision of an out-of-state dentist licensed in Alabama to be the unlicensed practice of dentistry.

57. The Board interprets the term “digital images” in Ala. Code § 34-9-6(7) to include the iTero’s digitally stored and processed photographs, even though the terms “digital imaging machine” and “digital images” are undefined and the statute was enacted long before digital cameras like the iTero were in use. Indeed, their broad interpretation would equally include images of the teeth taken by a smart phone.

58. The Board’s position also ignores the statutory exemption found in Ala. Code § 34-9-7(a)(5)—which specifically allows the use of digital imaging under the “supervision” of a licensed dentist without any geographic limitation—and instead argues that its own regulation which provides for stricter oversight, Ala. Admin. Code r. 270-X-3-.10, applies. *Compare* § 34-9-7(a)(5) (requires “supervision” and expressly promotes the practice of dentistry across state lines) *with* Ala. Admin. Code r. 270-X-3-.10 (requires “direct supervision” which is further defined as on-site supervision, the opposite of the practice of dentistry across state lines).

59. Despite the regulations promulgated by the Board regarding the taking of “digital images”, the simple fact remains that the Board has no authority over acts which do not and cannot constitute the practice of dentistry, such as the mere taking of photographs of teeth and gums, even if it is with a sophisticated camera. The taking of such photos is not a medical or dental procedure in that there is no evaluation or diagnosis involved in the mere taking of such photos. The

assessment and diagnosis related to the photographs is done exclusively by the state-licensed dentist.

60. The position the Board has taken with SmileDirect, assuming it has the authority to restrict the mere taking of digital photographs, contravenes the Dental Practice Act in multiple ways; including, the Alabama Legislature's stated finding of a public interest in and desire to promote technological advancements and the practice of dentistry across state lines. The Board's position also contravenes the exemption found in Ala. Code § 34-9-7(a)(5), which specifically allows the use of digital imaging under the "supervision" of a licensed dentist in a statute expressly promoting the interstate practice of dentistry through technology.

61. The Board's interpretation and application of Ala. Code § 34-9-6(7) and Ala. Admin Code r. 270-X-3-.10 will require digital photographs that create scans in Alabama to be made in a building where a licensed dentist is physically present, rather than by a trained employee in a SmileShop who provides those same digital photos to an Alabama-licensed dentist or orthodontist through SmileDirect's web-based platform, with the same level of supervision done remotely. The Board's self-serving interpretation makes the practice of dentistry across state lines a practical impossibility despite the stated purposes of the Act.

62. Given the Board's recent interpretation, SmileDirect will potentially be subject to the threat of: (1) Board action seeking to enjoin SmileDirect from conducting business in Alabama, *see* Ala. Code § 34-9-29, and (2) criminal prosecution, *see* Ala. Code § 34-9-5. Dr. Leeds will potentially be subject to the suspension or revocation of his Alabama license and to administrative fines. *See* Ala. Code § 34-9-18(a) and (b).

63. Moreover, such direct supervision is wholly unnecessary, irrational, and unjustified by any health and safety need because (1) the process is simple, only involving use of a pen-sized

camera wand that does not penetrate or cause any trauma to the teeth, gums or oral tissues whatsoever, (2) the disposable sleeve ensures there is no health or safety risk to a consumer, (3) the digital photography does not emit radiation or any other kind of potentially harmful penetrating rays, and (4) all photographs and the scan they create are later reviewed by an Alabama-licensed dentist or orthodontist to ensure the quality of the photographs, the digital photographic scan, a consumer's candidacy for treatment, and a proper treatment plan.

64. The Board's position fails to advance the public's welfare. To the contrary, it harms Alabama consumers by deliberately frustrating the practice of dentistry across state lines and severely impairing SmileDirect's ability to deliver affordable products and services to affiliated Alabama licensed dentists and orthodontists, who can then in turn pass these savings along to their patients.

65. Indeed, the Board's position makes it virtually impossible for Dr. Leeds and SmileDirect to serve Alabama dental patients across state lines and would require costly and prohibitive changes to SmileDirect's current business model.

66. The Board's position is not rationally based and does not serve a legitimate local purpose or public interest because it (1) is beyond the Board's rulemaking authority, (2) reduces Alabama's citizens' access to care, (3) increases the cost of digital photographic scans and overall orthodontic care, (4) does not protect the public, (5) inappropriately regulates a safe act, (6) distinguishes between persons employed by SmileDirect and non-dentists who perform digitally stored or processed photographic scans in the same building as a licensed dentist residing in Alabama, without a rational basis for such a distinction, and (7) deprives SmileDirect of the value of its business license and deprives SmileDirect's affiliated dentists licensed in Alabama, including

Dr. Leeds, of the value of their licenses, and otherwise deprives them of their constitutionally protected liberty and property interests.

The Relevant Market.

67. The “relevant market” in which to evaluate the anticompetitive effect of the conduct of Defendants is the market for aligner treatment for mild to moderate malocclusion in Alabama.

68. The relevant products in this market are aligner treatments for mild and moderate malocclusion. Clear aligners and traditional braces that use brackets and wires, as well as potentially non-fixed dental braces such as retainers, headgear, and palate expanders are viable substitutes for consumers to consider in the treatment of mild-to-moderate malocclusion.

69. The relevant geographic market is properly limited to Alabama. The Board purports to exercise authority over the provision of digital photographic scan services for clear aligner therapy treatment in Alabama. Furthermore, on information and belief, consumers in Alabama almost always seek clear aligner therapy treatment from local providers in the State. On information and belief, consumers who desire such services in Alabama do not travel out of state in any appreciable numbers to obtain clear aligner therapy treatment. If the price of clear aligner therapy treatment for mild-to-moderate malocclusion in Alabama increases as a result of actions of the Board, many consumers in Alabama will not seek clear aligner therapy treatment from providers in other states. Rather, such consumers will be forced to pay the higher prices for clear aligner therapy treatment and travel longer distances within Alabama to seek such services only from licensed dentists in Alabama.

The Board Exceeded Its Authority.

70. The Board is limited in its rulemaking authority—it may only regulate the practice of dentistry and those professionals who engage in the practice of dentistry. The Board has no

authority to regulate industries or activities that do not constitute the practice of dentistry or dental hygiene, such as dental support organizations, or those individuals who are not engaged in the practice of dentistry or dental hygiene. *See* Ala. Code § 39-9-40.

71. The Board has impermissibly exceeded the scope of its authority in attempting to regulate persons who merely take photographic images that are stored or processed digitally.

72. The self-serving decision of the Board is designed to protect the business interests of traditional dental and orthodontic practices.

The Board's Interpretation Will Reduce Alabama Citizens' Access to Care.

73. The position taken by the Board with respect to SmileDirect will diminish Alabama citizens' access to care by reducing the number of locations where photographs can be taken which are stored or processed digitally through the use of an iTero or other similar device for review by their treating state-licensed dentist to determine if they are a candidate for clear aligner therapy.

74. Approximately 63% of the counties in Alabama do not have a single licensed orthodontist.

75. Despite the massive volume of underserved patients in Alabama, the Board seeks to enforce the Dental Practice Act and its regulations in a manner that would needlessly complicate an otherwise safe act that an unlicensed person can perform in a variety of locations.

76. Under the Board's interpretation, SmileDirect would no longer be able to provide one of the key elements of the non-clinical support services it currently offers to Alabama-licensed dentists and orthodontists like Dr. Leeds, which allows them to provide affordable treatment to the dentists' patients. The dentist members of the Board, including those who actively promote the use of cameras similar to the iTero on their websites, however, would be able to use their own staff to continue to take the exact same photographs which are stored or processed digitally through the

use of an iTero or other similar device for their patients without any material difference in actual supervision. Moreover, no law or regulation would prohibit the dentist members of the Board who are not currently taking the exact same photographs which are stored or processed digitally through the use of an iTero or other similar device for their patients from providing such digital photographic scans in their offices in the future.

77. Despite current plans to open additional SmileShops across the State of Alabama, many in areas where people cannot easily access orthodontic care and treatment, SmileDirect would be forced to limit, if not entirely eliminate, its plans for increasing access to affordable orthodontic care across the State of Alabama if the Board's position is deemed valid.

78. As a result, rather than protect patients, the Board's decision will unnecessarily drive up costs and decrease access to care in the relevant market based on the mistaken belief that the mere taking of photographs which are stored or processed digitally through the use of an iTero or other similar device is a dental procedure and must be performed by, or directly supervised by, a dentist. Tellingly, the Board's position would not require that a licensed dentist visually monitor or observe the taking of these photographs; it requires only that a licensed dentist be in the same building at the time the photographs are being taken.

79. Taking photographs which are stored or processed digitally through the use of an iTero or other similar device of a consumer's teeth and gums is neither dangerous (as per Defendant Walker, it "is the size and shape of a pen" while Defendant Jackson, acknowledges it "is small, about the size of the [standard dental] mirror") nor risky (as per Defendant Walker, "It is covered with a disposable sheath, to ensure that no germs are transmitted from patient-to-patient"). It is nothing more than the taking of photographs. Nor does it require the knowledge, training, and education of a licensed dentist or orthodontist or even an extended duty dental

assistant to properly execute. Photographs of smiles, including visible teeth and gums, are taken by the public at large using cell phones every day. The Board's position logically means that even those digital images of teeth are the practice of dentistry—an absurd proposition.

80. The taking of digital photographs using today's technology such as the iTero or a cell phone is not even a dental procedure, but rather a non-invasive use of digital photographic technology to create an accurate three-dimensional model of a prospective patient's teeth, bite, gums, and palate. Trained staff such as those employed by SmileDirect are capable of accurately taking photographs which are stored or processed digitally through the use of an iTero or other similar device of a consumer's teeth and gums without the need for a dentist to be present, and the iTero presents no risk of harm to a consumer.

81. There is no known evidence that digital photographs taken under the "direct supervision" of a licensed dentist or orthodontist on site are somehow safer or more accurate than digitally stored or processed photographs taken without such "direct supervision."

The Board's Position Will Increase the Cost of Digital Photographic Scans and Overall Orthodontic Care.

82. The Board's position will also unnecessarily increase the cost of digital photographic scans and overall clear aligner therapy treatment for Alabama consumers by requiring highly paid personnel to be physically present during an otherwise safe, inexpensive and simple act. Many Alabama consumers also will incur increased costs by needing to travel to and pay for an office visit to a dentist or orthodontist, particularly when the office visit is not covered by insurance. This increase in cost will be borne by consumers, who will pay more for such services than they otherwise would need to pay.

83. Dr. Leeds and SmileDirect also will suffer significant economic injury and damage as a result of the Board's actions. They will suffer lost business that they would have obtained by offering services that are lower priced than those offered by in-state dentists and orthodontists.

84. Indeed, the only parties who benefit from the Board's misinterpretation of their authority and the Alabama regulations governing the practice of dentistry are the licensed dentists and orthodontists who are residents of Alabama and who offer, or will offer, such services in their own local offices, including members of the Board. In the absence of teledentistry competition from Dr. Leeds and SmileDirect, they will be able to charge higher total prices to consumers for clear aligner products, solely because a simple photo session must take place in their office. Such anticompetitive requirements drive up costs and entirely eliminate the ability of many citizens in Alabama to receive convenient, affordable care; indeed, care that has been proven to positively impact many other aspects of a person's overall health.

The Board's Interpretation Does Not Protect the Public.

85. The taking of digital photographs using an iTero or similar device is extremely safe. The process consists of using a wand with a camera at varying angles to photograph the teeth and tissue so as to get a more accurate and predictable model of the teeth and gums than physical impressions.

86. The technology of taking digital photographs to create a scan is extremely user-friendly, providing real time feedback to the user regarding the accuracy of the photographs and informing the user of where additional photographs are needed to complete the full scan.

87. This advanced process does not use any radiation and allows the patient's teeth and gums to be photographed without the patient experiencing any trauma, pain, or morbidity.

88. The iTero is also easy to clean between uses and thus presents no meaningful risk of cross-contamination as long as the person performing the photography removes and discards the disposable cover and wipes the wand with a disinfecting wipe after each use. To again quote Defendant Walker: “It is covered with a disposable sheath, to ensure that no germs are transmitted from patient-to-patient.” SmileDirect staff are carefully trained on these procedures and are required to follow them after each use of the iTero.

89. Given that the photographs which create these scans present no risk to consumers that direct supervision by a local dentist would eliminate, the Board’s position has no rational basis, and unnecessarily complicates a safe act by needlessly imposing regulatory burdens that do not provide any additional protection to the public.

90. Indeed, as noted above, SmileDirect has performed hundreds of thousands of digital photographic scans in existing SmileShops nationwide—and hundreds of digital photographic scans in Alabama alone—without receiving a single complaint of physical injury, infection, or other adverse patient outcome associated with the taking of these photographs.

The Board’s Position Places Unreasonable and Unnecessary Restraints on the Pursuit of Harmless, Useful Activities.

91. The Board seeks to disproportionately restrain the pursuit of safe activities by SmileDirect and Dr. Leeds.

92. In fact, the adoption of the Board’s position with respect to Ala. Code § 34-9-6(7) would necessitate the implausible finding that any person using a smart phone or camera to take any digital image of a person’s teeth and gums is practicing dentistry. This results in restrictions being placed on the mere taking of digital photographs that are equivalent to restrictions on the following procedures, all of which are more invasive and potentially dangerous and should require

medical/dental training and experience as opposed to the taking of digital photographs to create a scan:

- capturing a radiographic image using ionizing radiation (x-ray);
- removing sutures;
- applying topical anesthetic or other desensitizing agents;
- applying light-cured medicinal bonding agents;
- placing and removing alveolar socket dressings;
- removing excess cement with hand instruments; and
- assisting in the administration of nitrous oxide.

93. Moreover, the existing Alabama Dental Practice Act, Ala. Code § 34-9-1 *et seq.*, evidences a statutory intent that is at odds with the Board's current position that making photographs that are stored as digital images requires "direct supervision."

94. Specifically, almost all of the other conduct that the Board requires to be directly supervised by a licensed dentist involve (1) invasive procedures or (2) the administration of anesthesia.

95. Taking photographs which are stored or processed digitally through the use of an iTero or other similar device, however, is not threatening to patient safety.

96. In sum, the taking of photographs which are stored or processed digitally through the use of an iTero or other similar device does not constitute the practice of dentistry or dental hygiene and is not in need of oversight or regulation, let alone requiring direct supervision by a dentist. If anything, rules that proactively allow trained personnel to take photographs which are stored or processed digitally through the use of an iTero or other similar device to be reviewed by a licensed dental professional on their own are sufficient to protect patients while simultaneously

promoting increased access to care and lower cost to consumers in Alabama and the practice of dentistry across state lines by licensed dentists.

97. A copy of this Complaint is being served on the Office of the Attorney General of Alabama.

CAUSES OF ACTION

COUNT ONE: VIOLATION OF THE DORMANT COMMERCE CLAUSE AS TO DR. LEEDS (All Defendants)

98. Plaintiffs re-allege and incorporate paragraphs 1 through 97 as if fully set forth herein.

99. This Count is brought pursuant to 42 U.S.C. § 1983 as well as the Commerce Clause of the United States Constitution, Article I, Clause 8, which provides that “Congress shall have Power . . . [t]o regulate Commerce with foreign Nations, and among the several States”

100. Pursuant to the Commerce Clause’s dormant aspect, the Defendants cannot enact regulations that benefit in-state interests by burdening out-of-state competitors, as such regulations which unreasonably or unduly interfere with interstate commerce.

101. In combination, Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 facially discriminate against interstate commerce by requiring out-of-state dentists like Dr. Leeds to be physically present to provide “direct supervision” when digital photographic scans are being taken.

102. There is no legitimate local purpose that justifies substantially burdening Dr. Leeds’s practice by requiring a dentist onsite when digital photographs are taken with the iTero. As described above, the taking of photographs using the iTero is not a clinical procedure.

Furthermore, the iTero presents no risk to consumers that onsite supervision by a local dentist would eliminate.

103. Even if there were a legitimate local purpose for such a regulation, it would be adequately served by reasonable, nondiscriminatory alternatives.

104. In the alternative, even if Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10, taken together, were not facially discriminatory against out-of-state dentists, as interpreted to apply here by the Board, the burden they impose on commerce is clearly excessive in relation to the nonexistent putative local benefits.

105. Accordingly, this Court should grant declaratory and injunctive relief restraining Defendants' violation of the Commerce Clause and award Dr. Leeds attorneys' fees and costs.

**COUNT TWO: VIOLATION OF THE DORMANT COMMERCE CLAUSE
AS TO SMILEDIRECT
(All Defendants)**

106. Plaintiffs re-allege and incorporate paragraphs 1 through 105 as if fully set forth herein.

107. This Count is brought pursuant to 42 U.S.C. § 1983 as well as the Commerce Clause of the United States Constitution, Article I, Clause 8, which provides that "Congress shall have Power . . . [t]o regulate Commerce with foreign Nations, and among the several States"

108. Pursuant to the Commerce Clause's dormant aspect, the Defendants cannot enact regulations that benefit in-state interests by burdening out-of-state competitors, as such regulations unreasonably or unduly interfere with interstate commerce.

109. In combination, Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 disproportionately affect SmileDirect and its interstate operations, as an out-of-state company that provides a teledentistry platform for offsite dentists or orthodontists to review and approve digital

photographs taken at SmileShops. In practical operation and effect, Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 discriminate against out-of-state corporations like SmileDirect and protect domestic providers from lawful competition. This discrimination against SmileDirect as an out-of-state corporation violates its constitutional rights.

110. There is no legitimate local purpose or public interest that justifies substantially burdening SmileDirect's operations by requiring a dentist onsite for the taking of photographs which are stored or processed digitally through the use of an iTero or other similar device by SmileShop employees. As described above, the taking of these digital photos, in and of themselves, is not the practice of dentistry and the iTero presents no risk to consumers that direct supervision by a local dentist would eliminate.

111. Even if there were a legitimate local purpose or public interest for such a regulation, it would be adequately served by reasonable nondiscriminatory alternatives.

112. In the alternative, Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 discriminate against the emerging technology and teledentistry platform offered by out-of-state company SmileDirect, preventing it from pursuing its business model in Alabama. Given that there are no benefits to having a local dentist onsite to supervise inherently safe, digital photographs that create the scan, the burden imposed on commerce is clearly excessive in relation to the putative local benefits.

113. Accordingly, this Court should grant declaratory and injunctive relief restraining Defendants' violation of the Commerce Clause and award SmileDirect its attorneys' fees and costs.

**COUNT THREE: VIOLATION OF 15 U.S.C. § 1 AS TO DR. LEEDS
(Defendants Jackson, Walker, Beckham, Strickland, McIlwain, and Sims)**

114. Plaintiffs re-allege and incorporate paragraphs 1 through 113 as if fully set forth herein.

115. The Defendants entered a contract, combination, or conspiracy in restraint of trade and commerce to prevent Dr. Leeds from providing teledentistry services to Alabama patients. By requiring on-site supervision for the use of the iTero, Defendants have prevented Dr. Leeds from practicing dentistry for Alabama patients from out-of-state. Specifically, Defendants have prevented Dr. Leeds from utilizing SmileDirect's non-clinical support services to offer clear aligner therapy treatment in the relevant market. Defendants are essentially driving out a low-cost competitor who is utilizing a teledentistry platform to provide orthodontic services in the relevant market at a cheaper cost and forcing consumers to visit the offices of in-state dentists or orthodontists for orthodontic services at a higher cost. Defendants' restriction of the dental services provided by Alabama-licensed but out-of-state dentists like Dr. Leeds constitutes a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

116. In furtherance of their contract, combination, or conspiracy in restraint of trade, the Defendants have agreed and acted upon a policy of requiring dentists to be onsite when SmileDirect personnel use the iTero to take the digital photographs, thereby harming competition in the relevant market. This agreement among Defendants is expressed in Defendants cease and desist letter to SmileDirect and other actions taken in purported furtherance of Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 to preclude SmileDirect from allowing its trained staff to take digital photographs of teeth and gums.

117. As is evidenced by Defendants' actions in sending a cease and desist letter and email to SmileDirect as well as the telephone call with SmileDirect's representatives on October 9, 2018, Defendants demonstrated a unity of purpose, as well as common design and understanding, to reduce or eliminate competition in the relevant market.

118. As is evidenced by Defendants' actions in sending a cease and desist letter and email to SmileDirect as well as the telephone call with SmileDirect's representatives on October 9, 2018, the Defendants possessed, and still possess, a conscious commitment to a common scheme designed to achieve an unlawful objective.

119. The Defendants include six practicing dentists in the State of Alabama and their actions therefore constitute a continuing agreement, understanding, and concert of action among market participants.

120. The Defendants' actions have the purpose and effect of unreasonably restraining trade in the relevant market, the net effects of which are anticompetitive, and any purported procompetitive justifications are illegitimate and pretextual. The Defendants' actions have the following anticompetitive effects in the relevant market:

- preventing Alabama-licensed but out-of-state dentists from utilizing in-state digital photographs needed to provide clear aligner therapy treatment in Alabama;
- creating barriers to entry for out-of-state dentists seeking to enter the market for clear aligner therapy treatment in Alabama;
- reducing consumer choice and the availability of dentists to provide clear aligner therapy treatment to consumers in Alabama; and

- reducing incentives for innovation in the provision of clear aligner therapy treatment in Alabama via teledentistry.

121. Defendants' actions constitute a per se violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, because they are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality.

122. The Defendants' actions also constitute a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, under a "quick look" analysis because an observer with even a rudimentary understanding of economics could conclude that their actions would have an anticompetitive effect on consumers in the relevant market.

123. The Defendants' actions also constitute a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, under the Rule of Reason because the facts and circumstances reveal that they have an adverse impact on competition that cannot be justified as a procompetitive measure.

124. On their face, the Defendants' actions restrict, and are intended to restrict, the method of competing in the relevant market, thereby restricting the number of competitors and causing prices in the relevant market to rise, maintain, or stabilize above competitive levels. Defendants have market power in the relevant market and can enforce their output-restricting agreement by using the legal process of the State of Alabama to preclude entrance into the relevant market or to restrict the method of competition in the relevant market. Defendants can, and do, use investigators of the State of Alabama to locate persons who provide digital photograph services for offsite dentists and threaten to use the office of the District Attorney to enforce sanctions against any such individual or business, which results in harm to competition in the relevant market. The individual dentist Defendants are actual or potential participants in the relevant market

and have incentives to restrict competition in the relevant market, and no legitimate business justification exists for Defendants' agreement.

125. The Defendants' actions evidence predatory intent to deprive out-of-state dentists that utilize a new, more efficient method of competition of a fair opportunity to compete in the relevant market. Through their actions, Defendants intend to reduce the number of providers of clear aligner therapy treatment in Alabama and the output of such services. Defendants' actions do not enhance public health and safety in Alabama and do not serve any legitimate public purpose.

126. The regulation at issue was not supported by a clearly expressed state policy reflected in the relevant state statute at the time the regulation was issued, and therefore is preempted by Section 1 of the Sherman Act, 15 U.S.C. § 1.

127. As a direct, proximate, and foreseeable result of the Defendants' actions, Dr. Leeds has or will suffer damages and injury.

**COUNT FOUR: VIOLATION OF 15 U.S.C. § 1 AS TO SMILEDIRECT
(Defendants Jackson, Walker, Beckham, Strickland, McIlwain, and Sims)**

128. Plaintiffs re-allege and incorporate paragraphs 1 through 127 as if fully set forth herein.

129. The Defendants, by and through their anticompetitive actions as outlined herein, entered a contract, combination, or conspiracy in restraint of trade and commerce to prevent SmileDirect from opening and operating SmileShops in the relevant market. By preventing SmileDirect's SmileShops from operating in the state, the Defendants restrict SmileDirect from providing non-clinical support services to contractually affiliated dental practices, including the ability to offer the taking of photographs which are stored or processed digitally through the use of an iTero or other similar device in the state of Alabama. Defendants are essentially driving out

a low-cost competitor who provides a teledentistry platform for dentists and orthodontists to provide orthodontic services in the relevant market at a cheaper cost and forcing consumers to purchase orthodontic services at a higher cost. Defendants' restriction of the ability of SmileDirect to open and operate SmileShops in Alabama constitutes a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

130. In furtherance of their contract, combination or conspiracy in restraint of trade, the Defendants have agreed and acted upon a policy of excluding non-dentists from taking digital photographs to create scans without the direct supervision of dentists, thereby harming competition in the relevant market. This agreement among Defendants is expressed in Defendants' cease and desist letter and other actions taken in purported furtherance of Ala. Code § 34-9-6(7) and Ala. Admin. Code r 270-X-3-.10 to preclude SmileDirect from having trained iTero operators take photographs of teeth to be stored or processed digitally.

131. As is evidenced by Defendants' actions in sending a cease and desist letter and email to SmileDirect as well as the telephone call with SmileDirect's representatives on October 9, 2018, Defendants demonstrated a unity of purpose, as well as common design and understanding, to reduce or eliminate competition in the relevant market.

132. As is evidenced by Defendants' actions in sending a cease and desist letter and email to SmileDirect as well as the telephone call with SmileDirect's representative on October 9, 2018, the Defendants possessed, and still possess, a conscious commitment to a common scheme designed to achieve an unlawful objective.

133. The Defendants are practicing dentists in the State of Alabama and their actions therefore constitute a continuing agreement, understanding, and concert of action among market participants.

134. The Defendants' actions have the purpose and effect of unreasonably restraining trade in the relevant market, the net effects of which are anticompetitive, and any purported procompetitive justifications are illegitimate and pretextual. The Defendants' actions have the following anticompetitive effects in the relevant market:

- preventing and deterring the use of non-dentists for digital scan services needed to provide clear aligner therapy treatment in Alabama;
- creating barriers to entry for businesses seeking to enter the market for clear aligner therapy treatment in Alabama by blocking access to essential inputs;
- depriving consumers of the benefits of competition on price and quality for clear aligner therapy treatment in Alabama by causing Smile Direct and other new, efficient providers of non-clinical support services to dental practices that wish to offer clear aligner therapy treatment to shut down or incur higher costs;
- reducing consumer choice and the availability of clear aligner therapy treatment to consumers in Alabama;
- reducing incentives for innovation in the provision of clear aligner therapy treatment in Alabama; and
- increasing the prices that consumers in Alabama pay for clear aligner therapy treatment.

135. Defendants' actions constitute a per se violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, because they are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality.

136. The Defendants' actions also constitute a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, under a "quick look" analysis because an observer with even a rudimentary

understanding of economics could conclude that their actions would have an anticompetitive effect on consumers in the relevant market.

137. The Defendants' actions also constitute a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, under the Rule of Reason because the facts and circumstances reveal that they have an adverse impact on competition that cannot be justified as a procompetitive measure.

138. On their face, the Defendants' actions restrict, and are intended to restrict, the method of competing in the relevant market, thereby restricting the number of competitors and causing prices in the relevant market to rise, maintain, or stabilize above competitive levels. Defendants have market power in the relevant market and can enforce their output-restricting agreement by using the legal process of the State of Alabama to preclude entrance into the relevant market or to restrict the method of competition in the relevant market. Defendants can, and do, use investigators of the State of Alabama to locate persons who offer to take photographs which are stored or processed digitally through the use of an iTero or other similar device in contravention of their agreement that only licensed dentists (or those they directly supervise) can offer the service, and threaten to use the office of the District Attorney to enforce sanctions against any individual or business that operates in contravention of their agreement, which results in harm to competition in the relevant market. The individual dentist Defendants are actual or potential participants in the relevant market and have incentives to restrict competition in the relevant market, and no legitimate business justification exists for Defendants' agreement.

139. The Defendants' actions evidence predatory intent to deprive businesses that utilize a new, more efficient method of competition of a fair opportunity to compete in the relevant market. Through their actions, Defendants intend to reduce the number of providers of clear aligner

therapy treatment in Alabama and the output of such services. Defendants' actions do not enhance public health and safety in Alabama and do not serve any legitimate public purpose.

140. The regulation at issue was not supported by a clearly expressed state policy reflected in the relevant state statute at the time the regulation was issued, and therefore is preempted by the Sherman Act.

141. As a direct, proximate, and foreseeable result of the Defendants' actions, SmileDirect has or will suffer damages and injury.

**COUNT FIVE: VIOLATION OF EQUAL PROTECTION CLAUSE
AS TO DR. LEEDS
(All Defendants)**

142. Plaintiffs re-allege and incorporate paragraphs 1 through 141 as if fully set forth herein.

143. This Count is brought pursuant to the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution and 42 U.S.C. § 1983.

144. Pursuant to the Board's position, Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 create a distinction between Alabama-licensed dentists practicing in Alabama and Alabama-licensed dentists practicing out-of-state, without a rational basis for such a distinction, in violation of the rights of Dr. Leeds under the Equal Protection Clause.

145. The Equal Protection Clause of the Fourteenth Amendment does not allow government to treat similarly situated persons differently unless the reason for doing so bears a rational relationship to a legitimate governmental interest.

146. As detailed above, there is no rational basis for Alabama's distinction between Alabama-licensed dentists in Alabama who supervise the taking of photographs which are stored or processed digitally through the use of an iTero or other similar device on-site and Alabama-

licensed dentists practicing out of state who supervise the creation of digital photographic scans off-site. Accordingly, Dr. Leeds has been denied the equal protection of law.

147. Unless Defendants are enjoined from committing the above-described violations of the Equal Protection Clause of the Fourteenth Amendment, Dr. Leeds will suffer great and irreparable harm. As detailed above, in the absence of an injunction, Dr. Leeds will lose the ability to practice dentistry in Alabama via the taking of photographs which are stored or processed digitally through the use of an iTero or other similar device off-site at the SmileShop, which is a central, key component of his business.

148. Accordingly, this Court should grant declaratory and injunctive relief restraining Defendants' denial to Dr. Leeds of equal protection of the law and award Dr. Leeds's attorneys' fees and costs.

**COUNT SIX: VIOLATION OF EQUAL PROTECTION CLAUSE
AS TO SMILEDIRECT
(All Defendants)**

149. Plaintiffs re-allege and incorporate paragraphs 1 through 148 as if fully set forth herein.

150. This Count is brought pursuant to the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution and 42 U.S.C. § 1983.

151. Pursuant to the Board's position, Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 create a distinction between persons who take photographs which are then stored or processed digitally at SmileShops and persons who take photographs which are then stored or processed digitally while a licensed dentist is present in the office, without a rational basis for such a distinction, in violation of SmileDirect's rights under the Equal Protection Clause.

152. The Equal Protection Clause of the Fourteenth Amendment does not allow government to treat similarly situated persons differently unless the reason for doing so bears a rational relationship to a legitimate governmental interest.

153. As detailed above, there is no rational basis for Alabama's distinction between persons and entities who take photographs of teeth and gums which are then stored or processed digitally and are supervised by off-site licensed dentists, on the one hand, and persons and entities who offer the identical service with a local licensed dentist physically present in the same building, on the other hand. This is particularly true because the onsite dentist is not required by the regulation to even observe the taking of photographs in question while it is happening. Accordingly, SmileDirect has been denied equal protection of the law.

154. Unless Defendants are enjoined from committing the above-described violations of the Equal Protection Clause of the Fourteenth Amendment, SmileDirect will suffer great and irreparable harm. As detailed above, in the absence of an injunction, SmileDirect will be prohibited from employing staff to perform digital photographic scans and will face the possibility of enforcement action and possible criminal penalties if it continues to do so.

155. Accordingly, this Court should grant declaratory and injunctive relief restraining Defendants' denial to SmileDirect of equal protection of the law and award SmileDirect attorneys' fees and costs.

**COUNT SEVEN: VIOLATION OF SUBSTANTIVE DUE PROCESS
AS TO DR. LEEDS
(All Defendants)**

156. Plaintiffs re-allege and incorporate paragraphs 1 through 155 as if fully set forth herein.

157. This Count is brought pursuant to the Due Process Clause of the Fourteenth Amendment and 42 U.S.C. § 1983.

158. Dr. Leeds possesses liberty and property interests in the ability to pursue his chosen profession, as a licensed out-of-state dentist providing teledentistry services to Alabama residents across state lines, subject only to regulations that are rationally related to a legitimate government interest.

159. The Board's position regarding and enforcement of Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 deprives Dr. Leeds of his liberty and property interests that are protected by the Due Process Clause by imposing restrictions on his ability to serve patients from out-of-state—restrictions which are not rationally related to any legitimate governmental interest. Indeed, Dr. Leeds would be forced to stop providing Alabama residents affordable clear aligner services if the Board is permitted to enforce Ala. Code § 34-9-6(7) and Alabama Admin. Code r. 270-X-3-.10 under their current interpretation.

160. As detailed above, The Board's position regarding and enforcement of Ala. Code § 34-9-6(7) and Alabama Admin. Code r. 270-X-3-.10 which Defendants have undertaken under color of State law, is not rationally related to any legitimate government interest.

161. Unless Defendants are enjoined from committing the above-described violations of the Fourteenth Amendment, Dr. Leeds will suffer great and irreparable harm. As detailed above, in the absence of an injunction, Dr. Leeds will lose the ability to practice dentistry in Alabama via the photography performed off-site at the SmileShop.

162. Accordingly, this Court should grant declaratory and injunctive relief restraining Defendants' denial to Dr. Leeds of Due Process and award Dr. Leeds attorneys' fees and costs.

**COUNT EIGHT: VIOLATION OF SUBSTANTIVE DUE PROCESS
AS TO SMILEDIRECT
(All Defendants)**

163. Plaintiffs re-allege and incorporate paragraphs 1 through 162 as if fully set forth herein.

164. This Count is brought pursuant to the Due Process Clause of the Fourteenth Amendment and 42 U.S.C. § 1983.

165. SmileDirect possesses liberty and property interests in the ability to conduct a business that provides non-clinical support services to contractually-affiliated dental practices, including the ability to take photographs of teeth and gums which are then stored or processed digitally, subject only to regulations that are rationally related to a legitimate government interest.

166. The Board's position regarding and enforcement of Ala. Code § 34-9-6(7) and Alabama Admin. Code r. 270-X-3-.10 deprives SmileDirect of its liberty and property interests that are protected by the Due Process Clause by imposing restrictions on its ability to take photographs of teeth and gums which are then stored or processed digitally that are not rationally related to any legitimate governmental interest. Indeed, as described above, SmileDirect would be forced to limit, if not entirely eliminate, its plans for increasing access to affordable orthodontic care across the State of Alabama if the Board is permitted to enforce Ala. Code § 34-9-6(7) and Alabama Admin. Code r. 270-X-3-.10 under their current interpretation.

167. As detailed above, the Board's position regarding and enforcement of Ala. Code § 34-9-6(7) and Alabama Admin. Code r. 270-X-3-.10, which Defendants have undertaken under color of State law, is not rationally related to any legitimate government interest.

168. Unless Defendants are enjoined from committing the above-described violations of the Fourteenth Amendment, SmileDirect will suffer great and irreparable harm. As detailed above,

in the absence of an injunction, SmileDirect will be prohibited from employing trained personnel to take photographic scans in its SmileShops, and will face the possibility of enforcement action and possible criminal penalties if it continues to do so.

169. Accordingly, this Court should grant declaratory and injunctive relief restraining Defendants' denial to SmileDirect of Due Process and award SmileDirect attorneys' fees and costs.

**COUNT NINE: VIOLATION OF ALABAMA DUE PROCESS GUARANTEE
(All Defendants)**

170. Plaintiffs incorporate and reallege the allegations of Paragraphs 1 through 169 as if fully set forth herein.

171. SmileDirect and Dr. Leeds bring this count for declaratory judgment pursuant to 28 U.S.C. § 2201.

172. SmileDirect and Dr. Leeds bring this count pursuant to the right to due process guaranteed under Article I, Sections 6 and 13 of the Alabama Constitution of 1901. The Due Process guarantee protects against undue interference with private business and imposition of unnecessary and unreasonable restraints upon the pursuit of useful activities.

173. The requirement of "direct" supervision imposed by the Board's regulation is a violation of the due process rights of SmileDirect and Dr. Leeds.

174. To the extent that the Dental Practice Act itself were construed to require in-office supervision of the taking of photographs of teeth and gums which are then processed digitally conducted by SmileDirect SmileShop employees then the Act also would violate the due process rights of SmileDirect and Dr. Leeds.

175. An actual controversy has arisen between SmileDirect, Dr. Leeds, and Defendants concerning the Board's position with regard to Ala. Code § 34-9-6(7) and Ala. Admin. Code r.

270-X-3-.10. Plaintiffs' due process rights are in actual jeopardy of being harmed by the Board's enforcement of Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3.10. The imminent enforcement of those provisions immediately, definitively, and adversely affects the interests of SmileDirect and Dr. Leeds because the Board's enforcement of Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3.10 against SmileDirect and Dr. Leeds effectively eliminates SmileDirect's ability to take photographs of consumers' teeth and gums which are then stored or processed digitally at its SmileShops and Dr. Leeds' ability to provide services to patients with mild to moderate malocclusion who wish to use clear plastic aligners in the State of Alabama.

176. SmileDirect and Dr. Leeds seek a declaration from this Court pursuant to 28 U.S.C. § 2201 that requiring a dentist's on-site supervision for the use of the iTero violates Plaintiffs' right to Due Process guaranteed under Article I, Sections 6 and 13 of the Alabama Constitution of 1901.

**COUNT TEN: DECLARATORY JUDGMENT
(All Defendants)**

177. Plaintiffs re-allege and incorporate paragraphs 1 through 176 as if fully set forth herein.

178. SmileDirect and Dr. Leeds bring this Count for declaratory judgment pursuant to 28 U.S.C. § 2201.

179. Requiring a dentist's on-site supervision of the taking of photographs of teeth and gums which are then stored or processed digitally is inconsistent with and directly contrary to the Alabama Dental Practice Act.

- a. The Board's application of Ala. Admin Code r. 270-X-3-.10 to require SmileDirect to have a dentist on-site to supervise the use of the iTero is

directly contrary to and inconsistent with the stated statutory purposes of the Dental Practice Act. Namely, it is antithetical to the public interest in technological advancements and in advancing the practice of dentistry across state lines.

- b. The Board's application of Ala. Admin Code r. 270-X-3-.10 to require SmileDirect to have a dentist on-site to supervise the use of the iTero is inconsistent with Ala. Code § 34-9-7(a)(5) which specifically exempts SmileDirect's conduct from the unauthorized practice of dentistry.

180. Further, the Board's interpretation of the undefined term "digital imaging" in Ala. Code § 34-9-6(7) to encompass the type of visual photograph technology used by the iTero would lead to the absurd result of any digital photography of teeth—even with a smart phone—constituting the practice of dentistry in Alabama.

181. This Court is authorized to "declare the rights and other legal relations of any interested party seeking such declaration" "in a case of actual controversy within its jurisdiction." 28 U.S.C. § 2201.

182. As set forth above, there is an "actual controversy" between Plaintiffs and the Board with respect to enforcement of Ala. Code § 34-9-6(7) against SmileDirect. The Board's requirement that SmileDirect have a dentist on-site to supervise the taking of photographs of teeth and gums which are then stored or processed digitally, definitively, and adversely affects SmileDirect's interests because it effectively eliminates SmileDirect's ability to provide low-cost digital photographic scans at its SmileShops in the State of Alabama, and it affects Dr. Leeds' interest because it prevents him from practicing dentistry across state lines. The Board's enforcement of Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3.10 against SmileDirect

will reduce Alabama citizens' access to care and increase the cost of digital photographic scans and clear aligner therapy treatment, does not protect the public, and would disproportionately regulate a safe act.

183. Accordingly, SmileDirect seeks declarations from this Court pursuant to 28 U.S.C. § 2201 that (1) the Alabama Dental Practice Act does not require a dentist's on-site supervision of the taking of photographs which are then stored or processed digitally through the use of an iTero or other similar camera; and (2) Ala. Admin. Code r. 270-X-3-.10 is void insofar as it requires a dentist's on-site supervision of the taking of photographs which are then stored or processed digitally through the use of an iTero or other similar camera.

**COUNT ELEVEN: PRELIMINARY AND PERMANENT INJUNCTION
(All Defendants)**

184. Plaintiffs re-allege and incorporate paragraphs 1 through 183 as if fully set forth herein.

185. If the Board enforces Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 to require a dentist's on-site supervision for the taking of photographs of teeth and gums which are then stored or processed digitally, Plaintiffs will suffer immediate injury and damage, including the threat of criminal prosecution and the inability to operate their business models in Alabama, and will continue during the pendency of this lawsuit to suffer additional damage if Defendants are not enjoined from enforcing Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 to require a dentist's on-site supervision for the taking of photographs which are then stored or processed digitally through the use of an iTero or other similar camera.

186. There is a substantial likelihood that Plaintiffs will prevail on the merits of their claims for the reasons set out above.

187. Immediate and substantial harm will result to Plaintiffs unless the Court restrains and enjoins Defendants from enforcing Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 to require a dentist's on-site supervision for the taking of photographs of teeth and gums which are then stored or processed digitally. SmileDirect and Dr. Leeds have no adequate legal remedy under the circumstances here presented: prohibiting Defendants from enforcing Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 to require a dentist's on-site supervision for the taking of photographs which are then stored or processed digitally through the use of an iTero or other similar camera is the only way to protect Plaintiffs' interests fairly and adequately.

188. The public interest will only be served by the issuance of preliminary and permanent injunctive relief. Without such relief, SmileDirect will be deprived of the use of its business model in Alabama of having trained personnel in its SmileShops take photographs of teeth and gums which are then stored or processed digitally locally for off-site dentists—precisely the business model that allows SmileDirect and its contractually affiliated dental practices to lower the cost, and increase the availability, of clear aligner therapy treatment to consumers across Alabama. Without such relief, Dr. Leeds will be deprived of the ability to practice dentistry across state lines as intended by the Act, and the ability to provide services to patients with mild to moderate malocclusion who wish to use clear plastic aligners in the State of Alabama.

189. A preliminary and permanent injunction are therefore appropriate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request relief as follows:

(a) Preliminarily and permanently enjoin the Defendants from enforcing Ala. Code § 34-9-6(7) and Ala. Admin. Code r. 270-X-3-.10 against Dr. Leeds and SmileDirect to require a

dentist's on-site supervision of the taking of digital photographs which are then stored or processed digitally through the use of an iTero or other similar camera;

(b) Declare that the Alabama Dental Practice Act, Ala. Code § 34-9-1 *et seq.*, does not require a dentist's on-site supervision of the taking of photographs which are then stored or processed digitally through the use of an iTero or other similar camera;

(c) Declare that Ala. Admin. Code r. 270-X-3-.10 is void insofar as it requires a dentist's on-site supervision of the taking of photographs which are then stored or processed digitally through the use of an iTero or other similar camera;

(d) Award reasonable attorneys' fees, costs, and expenses in this action pursuant to 15 U.S.C. § 15 and 42 U.S.C. § 1988; and

(e) Award such further relief as the Court deems just and proper.

JURY DEMAND

In accordance with Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs respectfully demand a jury trial of any and all issues in this action so triable of right.

Respectfully submitted this 12th day of October, 2018.

s/ Matthew H. Lembke

Matthew H. Lembke

OF COUNSEL:

Matthew H. Lembke (ASB-3922-M53D)
David G. Hymer (ASB-3922-M53D)
Michael R. Pennington (ASB-0178-T63M)
Brad Robertson (ASB-3856-Z12S)
BRADLEY ARANT BOULT CUMMINGS LLP
1819 Fifth Avenue North
Birmingham, AL 35203-2119
Phone: (205) 521-8000
Facsimile: (205) 521-8800
mlembke@bradley.com
dhymer@bradley.com
mpennington@bradley.com
brobertson@bradley.com